g 30941

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-02-29

February 13, 2002

James R. Hachey, Jr., President
The Lobster Pound, Incorporated
1213 North Central Avenue
Kissimmee, Florida 34741

Dear Mr. Hachey:

We inspected your seafood processing plant, located at the above address, on March 27, 30, and April 2, 2001. We regret the delay in our review and evaluation of the inspectional findings. The inspection revealed that you continue to have serious deviations from the Seafood HACCP Regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your refrigerated canned pasteurized crabmeat, fresh histamine producing fish and cooked frozen or refrigerated lobster to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the Seafood HACCP Regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

> You must have a HACCP plan to control the food safety hazards reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for refrigerated canned pasteurized crabmeat to control the food safety hazard of *C. botulinum* toxin formation.
>
> You must have a HACCP plan that lists the food safety hazards reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). However, your firm's HACCP plan for fresh fish, including Mahi-Mahi and Tuna, does not list the food safety hazard of scombrotoxin (histamine) formation.

Chapters 7 and 13 of the FDA Fish & Fisheries Products Hazards & Controls Guidance: *Third Edition, June 2001*, provides examples and guidelines to assist your firm in establishing controls for the food safety hazards of scombrotoxin (histamine) formation and *C. botulinum* toxin formation.

You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for cooked frozen or cooked refrigerated lobsters does not list critical limits for cooler temperature and adequate ice at the storage critical control point to control the food safety hazard of pathogen growth and toxin formation. This deviation was previously brought to your attention in or letter of January 28, 1999.

You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the cook weaks critical control point listed in your HACCP plan for cooked frozen or cooked refrigerated lobsters to control the food safety hazard of pathogen growth and toxin formation.

You must maintain sanitation control records that document the monitoring and correction of sanitation conditions and practices during processing, to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation control records. This deviation was previously brought to your attention in or letter of January 28, 1999.

In addition, your firm's HACCP plan for cooked frozen or cooked refrigerated lobster lists a critical limit at the receiving critical control point that states [redacted] The critical limit should state that no dead lobsters will be accepted. Lobsters destined for human consumption must be processed from live lobsters. Any animal that has died from any means other than slaughter is considered adulterated within the meaning of Section 402(a)(5) of the Act.

Your HACCP plan above also lists a critical limit of [redacted] degrees for [redacted] minutes for [redacted] lobsters at the cook weaks critical control point and does not specify a vacuum. Your cooking employee told our investigator that he is actually cooking up to [redacted] pounds of lobsters at [redacted] degrees and [redacted] of vacuum for [redacted] minutes. Your HACCP plan should be revised to reflect the actual cook procedure being used. We note that the manufacturer of your steamer recommends a cook of 212 degrees for 9-10 minutes for lobsters and states that vacuum varies with cooking temperature and would be near zero at 212 degrees.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your seafood products and/or enjoin your firm from operating.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your firm operates in compliance with the Act, the Seafood HACCP Regulations and the Good Manufacturing Practice (GMP) Regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of your revised HACCP plan, monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Jimmy E. Walthall, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Walthall at (407) 475-4731.

Sincerely,

Donna Sangre

for Emma R. Singleton
Director, Florida District